Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in February 2002.

New Approvals

ANADA Number: 200-301

Pioneer Product:	009-782
Trade Name:	Privasan™ Antiseptic Ointment
Ingredients:	Chlorhexidine acetate
Sponsor:	First Priority, Inc.
Approval Date:	November 6, 2001
Status:	Over-the-counter
Route:	Topical
Species:	Dogs, cats, horses (not for human consumption)
Drug Form:	Ointment
Concentration:	1%
Indications:	As a topical antiseptic for surface wounds.

21CFR 524.402

NADA Number: 141-192

Trade Name:	Ralgro® L.A.
Ingredients:	Zeranol
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	November 1, 2001
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Pasture cattle (slaughter, stocker, feeder steers and heifers)
Drug Form:	Implant
Concentration:	138 milligrams per implant
Indications:	For increased rate of weight gain for up to 210 days
Tolerance:	21CFR 556.760 Zeranol: A tolerance for total zeranol residues in uncooked edible tissues of cattle is not needed. The Acceptable Daily Intake is 0.00125 milligrams per kilogram of body weight per day.
Withdrawal:	Zero days
Exclusivity:	3 years

21CFR 522.2680 and *556.760*

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-180

Trade Name:	Torpex™		
Ingredients:	Albuterol sulfate		
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.		
Approval Date:	November 16, 2001		
Status:	Prescription only		
Route:	Intranasal		
Species:	Horses		
Drug Form:	Liquid (aerosol)		
Concentration:	120 micrograms per actuation (puff)		
Indications:	For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction.		
Patent Number:	5,225,183	Expiration date:	July 6, 2010
	5,695,743		July 6, 2010
	5,439,670		July 6, 2010
	5,766,573		July 6, 2010
	5,605,674		February 25, 2014
	5,666,948		September 16, 2014
Exclusivity:	5 years		

21CFR 529.40

Supplemental Approvals

ANADA Number: 200-066

This supplemental application provides for a revised withdrawal time for use of oxytetracycline soluble powder in the drinking water of turkeys and swine.

Trade Name:	Agrimycin® 343
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Agri Laboratories, Ltd.
Approval Date:	October 4, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Turkeys, swine
Drug Form:	Powder
Concentration:	1 gram oxytetracycline hydrochloride activity per 1.32 grams powder
Indications:	**Turkeys:** For control of: hexamitiasis caused by *Hexamita meleagridis;* infectious synovitis caused by *Mycoplasma synoviae,* susceptible to oxytetracycline. **Growing turkeys:** For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline. **Swine**: For the control and treatment of the following diseases: Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, susceptible to oxytetracycline. **Breeding swine:** Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*, susceptible to oxytetracycline.
Tolerance:	21CFR 556.500 Oxytetracycline: Tolerances are established for the sum or tetracycline residues in tissues of swine and turkeys as follows: 2 parts per million in muscle, 6 parts per million in liver, 12 parts per million in fat and kidney. The Acceptable Daily Intake for total tetracycline residues is 25 micrograms per kilogram of body weight per day.
Withdrawal:	Zero days

21CFR 520.1660d

NADA Number: 140-992

This supplemental application provides for a new concentration of trenbolone acetate and estradiol implant for use in feedlot heifers for increased rate of weight gain and improved feed efficiency.

Trade Name:	Revalor®-200
Ingredients:	Trenbolone acetate, estradiol
Sponsor:	Intervet, Inc.
Approval Date:	December 6, 2001
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle (heifers fed in confinement for slaughter)
Drug Form:	Implant (ear)
Concentration:	200 milligrams trenbolone acetate and 20 milligrams estradiol per implant
Indications:	For increased rate of weight gain and improved feed efficiency
Tolerance:	21CFR 556.240 Estradiol: Residues for estradiol and related esters may not exceed the following increments above the concentration of estradiol naturally present in untreated animals: In the uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion in muscle, 480 parts per trillion in fat, 360 parts per trillion in kidney, and 240 parts per trillion in liver. 21CFR 556.739 Trenbolone: A tolerance for total residues in uncooked edible tissues of cattle is not needed. An Acceptable Daily Intake of 0.4 micrograms per kilogram of body weight per day has been established.
Withdrawal:	Zero days
Exclusivity:	3 years

21CFR 522.2477

NADA Number: 141-111

This supplemental application provides for a once daily, 2-milligram per pound dosage.

Trade Name:	Rimadyl ® Chewable Tablets		
Ingredients:	Carprofen		
Sponsor:	Pfizer, Inc.		
Approval Date:	November 26, 2001		
Status:	Prescription only		
Route:	Oral		
Species:	Dogs		
Drug Form:	Tablet		
Concentration:	25, 75, and 100 milligrams per tablet		
Indications:	For the relief of pain and inflammation associated with osteoarthritis.		
Patent Numbers:	4,264,500	Expiration Date:	February 28, 2003
	6,013,808		April 15, 2019

21CFR 520.309

NADA Number: 141-063

This supplemental application provides for a change in nomenclature in a pathogen genus from *Pasteurella haemolytica* to *Mannheimia haemolytica* on labeling.

Trade Name:	Nuflor® Injectable Solution
Ingredients:	Florfenicol
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	November 8, 2001
Status:	Prescription only
Route:	Intramuscular or subcutaneous
Species:	Cattle
Drug Form:	Liquid (solution)
Concentration:	300 milligrams per milliter
Indications:	For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica, Pasteurella multocida,* and *Haemophilus somnus,* and bovine interdigital phegmon (foot rot) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. Also, indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica, Pasteurella multocida,* and *Haemophilus somnus*.
Tolerance:	21CFR 556.283 Florfenicol: Tolerances of 3.7 parts per million for florfenicol amine (marker residue) in liver (target tissue) and 0.3 part per million in muscle are established in cattle.
Withdrawal:	28 days before slaughter if given IM; 38 days if given SQ
Patent Numbers:	5,082,863 Expiration Date: January 21, 2009

21CFR 522.955

NADA Number: 141-085

This supplemental application provides for using single ingredient bacitracin methylene disalicylate and zoalene Type A Medicated Articles to make a two-way combination drug Type C medicated feeds in an additional species, chickens (replacements and broilers).

Trade Name:	Zoamix® + BMD®
Ingredients:	Zoalene, bacitracin methylene disalicylate
Sponsor:	Alpharma, Inc.
Approval Date:	November 30, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Replacement chickens and broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feeds.
Concentration:	Zoalene 113.5 grams activity per pound of Type A Medicated Article; bacitracin methylene disalicylate 10, 25, 30, 40, 50, 60, or 75 grams activity per pound of Type A Medicated Article.
Indications:	For the development of active immunity to coccidiosis and as an aid in the prevention and control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin in replacement chickens. Also for the prevention and control of coccidiosis and as an aid in the prevention and control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin in broiler chickens.
Tolerance:	21CFR 556.770 Zoalene: Tolerances are established for residues of zoalene (3,5-dinitro-o-toluamide) and its metabolite 3-amino-5-nitro-o-toluamide in chickens (edible tissues) as follows: 6 parts per million in uncooked liver and kidney, 3 parts per million in uncooked muscle tissue and 2 parts per million in uncooked fat. 21CFR 556.70 Bacitracin: The tolerance for residues of bacitracin from zinc bacitracin or bacitracin methylene disalicylate in uncooked edible tissues of chickens and eggs is 0.5 part per million.
Withdrawal:	Zero days

21CFR 558.680

NADA Number: 139-472

This supplemental application provides for use of approved tiamulin Type A Medicated Articles to make Type B and C medicated feeds use for control of porcine proliferative enteropathies (ileitis) in swine.

Trade Name:	Denagard® Medicated Premix
Ingredients:	Tiamulin
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	November 26, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Swine (under 250 pounds)
Drug Form:	Type A Medicated Articles to make Type B and C medicated feeds.
Concentration:	Type A Medicated Article containing 10 grams tiamulin activity per pound
Indications:	For increased rate of weight gain and improved feed efficiency, for treatment and control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin, and for the control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.
Tolerance:	21CFR 556.738 Tiamulin: A tolerance of 0.6 part per million is established for 8-alpha-hydroxymutilin (marker compound) in liver (target tissue).
Withdrawal:	2 days
Exclusivity:	3 years

21CFR 558.600

Suitability Petition Action

Number:	01P-0385/CP1
Sponsor:	Cross Vetpharm Group Ltd.
Petition:	Request permission to file an ANADA for a generic new animal drug oxytetracycline which differs from the pioneer product, Medamycin® Injectable, Boehringer Ingelheim Vetmedica, Inc., NADA 108-963, by the following characteristics: The generic product will consist of a different concentration (300 mg/ml) from the pioneer.
Action:	Denied on February 14, 2002.

Notice of Hearing

In the Federal Register of February 20, 2002 (67 FR 7700) the Food and Drug Administration announced a hearing on a proposal to withdraw approval of a new animal drug application (NADA). This notice of hearing (NOH) provides factual and legal information concerning CVM's proposal to withdraw the NADA and identifies the factual issues that will be subject to evidentiary hearing. A prehearing conference will be held on April 8, 2002. Any person wishing to participate shall submit written notice of participation by March 22, 2002. Submit to : Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All submissions must reference docket number 00N-1571.

NADA Number: 140-828

Tradename:	Baytril® 2.3% Concentrate Antimicrobial Solution
Sponsor:	Bayer Corp.

Final Rule

The Food and Drug Administration is issuing an order prohibiting the extralabel use of topical nitrofuran animal and human drugs in food-producing animals. This order has been issued based on evidence that extralabel use of topical nitrofuran drugs in food-producing animals may result in the presence of residues that have been determined to be carcinogenic and unsafe. Such extralabel use "presents a risk to the public health" for the purposes of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). This rule is effective May 7, 2002.